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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,979	01/16/2004	Frederick M. Ausubel	00786/408002	8737

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EXAMINER	
ROBINSON, HOPE A	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/758,979	AUSUBEL ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-100* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction/Election

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claim 1 is drawn to an isolated polypeptide (SEQ ID NO:3), classified in class 530, subclass 350.
2. Claims 2-3 are drawn to an isolated polynucleotide (SEQ ID NO:2), classified in class 536, subclass 23.1.
3. Claims 4-5 are drawn to a method of screening a compound for effectiveness as an antagonist, pertaining to SEQ ID NO:3, classified in class 435, subclass 7.1.
4. Claims 6-7 are drawn to a method for an antagonist compound for effectiveness in altering expression of a target nucleic acid, pertaining to SEQ ID NO:2, classified in class 435, subclass 6.
5. Claim 8 is drawn to a method for treatment of an individual having need to inhibit the polypeptide, pertaining to SEQ ID NO:3, classified in class 514, subclass 2.
6. Claim 9 is drawn to a vaccine, pertaining to SEQ ID NO:3, classified in class 435, subclass 43.
7. Claim 10 is drawn to a method of preventing or treating a microbial infection, pertaining to SEQ ID NO:3, classified in class 514, subclass 12.
8. Claim 11 is drawn to an isolated polypeptide (SEQ ID NO:15), classified in class 530, subclass 350.

9. Claims 12-13 are drawn to an isolated polynucleotide (SEQ ID NO:14), classified in class 536, subclass 23.1.

10. Claims 14-15 are drawn to a method of screening a compound for effectiveness as an antagonist, pertaining to SEQ ID NO:15, classified in class 435, subclass 7.1.

11. Claims 16-17 are drawn to a method for an antagonist compound for effectiveness in altering expression of a target nucleic acid, pertaining to SEQ ID NO:14, classified in class 435, subclass 6.

12. Claim 18 is drawn to a method for treatment of an individual having need to inhibit the polypeptide, pertaining to SEQ ID NO:15, classified in class 514, subclass 2.

13. Claim 19 is drawn to a vaccine, pertaining to SEQ ID NO:15, classified in class 435, subclass 43.

14. Claim 20 is drawn to a method of preventing or treating a microbial infection, pertaining to SEQ ID NO:15, classified in class 514, subclass 12.

15. Claim 21 is drawn to an isolated polypeptide (SEQ ID NO:18), classified in class 530, subclass 350.

16. Claims 22-23 are drawn to an isolated polynucleotide (SEQ ID NO:17), classified in class 536, subclass 23.1.

17. Claims 24-25 are drawn to a method of screening a compound for effectiveness as an antagonist, pertaining to SEQ ID NO:18, classified in class 435, subclass 7.1.

18. Claims 26-27 are drawn to a method for an antagonist compound for effectiveness in altering expression of a target nucleic acid, pertaining to SEQ ID NO:17 classified in class 435, subclass 6.

19. Claim 28 is drawn to a method for treatment of an individual having need to inhibit the polypeptide, pertaining to SEQ ID NO:18, classified in class 514, subclass 2.

20. Claim 29 is drawn to a vaccine, pertaining to SEQ ID NO:18, classified in class 435, subclass 43.

21. Claim 30 is drawn to a method of preventing or treating a microbial infection, pertaining to SEQ ID NO:18, classified in class 514, subclass 12.

22. Claim 31 is drawn to an isolated polypeptide (SEQ ID NO:30), classified in class 530, subclass 350.

23. Claims 32-33 are drawn to an isolated polynucleotide (SEQ ID NO:29), classified in class 536, subclass 23.1.

24. Claims 34-35 are drawn to a method of screening a compound for effectiveness as an antagonist, pertaining to SEQ ID NO:30, classified in class 435, subclass 7.1.

25. Claims 36-37 are drawn to a method for an antagonist compound for effectiveness in altering expression of a target nucleic acid, pertaining to SEQ ID NO:29, classified in class 435, subclass 6.

26. Claim 38 is drawn to a method for treatment of an individual having need to inhibit the polypeptide, pertaining to SEQ ID NO:30, classified in class 514, subclass 2.

27. Claim 39 is drawn to a vaccine, pertaining to SEQ ID NO:30, classified in class 435, subclass 43.

28. Claim 40 is drawn to a method of preventing or treating a microbial infection, pertaining to SEQ ID NO:30, classified in class 514, subclass 12.

29. Claim 41 is drawn to an isolated polypeptide (SEQ ID NO:6), classified in class 530, subclass 350.

30. Claims 42-43 are drawn to an isolated polynucleotide (SEQ ID NO:5), classified in class 536, subclass 23.1.

31. Claims 44-45 are drawn to a method of screening a compound for effectiveness as an antagonist, pertaining to SEQ ID NO:6, classified in class 435, subclass 7.1.

32. Claims 46-47 are drawn to a method for an antagonist compound for effectiveness in altering expression of a target nucleic acid, pertaining to SEQ ID NO:5, classified in class 435, subclass 6.

33. Claim 48 is drawn to a method for treatment of an individual having need to inhibit the polypeptide, pertaining to SEQ ID NO:6, classified in class 514, subclass 2.

34. Claim 49 is drawn to a vaccine, pertaining to SEQ ID NO:6, classified in class 435, subclass 43.

35. Claim 50 is drawn to a method of preventing or treating microbial infection, classified in class 514, subclass 12.

36. Claim 51 is drawn to an isolated polypeptide (SEQ ID NO:9), classified in class 530, subclass 350.

37. Claims 52-53 are drawn to an isolated polynucleotide (SEQ ID NO:8), classified in class 536, subclass 23.1.

38. Claims 54-55 are drawn to a method of screening a compound for effectiveness as an antagonist, pertaining to SEQ ID NO:9, classified in class 435, subclass 7.1.

39. Claims 56-57 are drawn to a method for an antagonist compound for effectiveness in altering expression of a target nucleic acid, pertaining to SEQ ID NO:8, classified in class 435, subclass 6.

40. Claim 58 is drawn to a method for treatment of an individual having need to inhibit the polypeptide, pertaining to SEQ ID NO:9, classified in class 514, subclass 2.

41. Claim 59 is drawn to a vaccine, pertaining to SEQ ID NO:9, classified in class 435, subclass 43.

42. Claim 60 is drawn to a method of preventing or treating a microbial infection, pertaining to SEQ ID NO:3, classified in class 514, subclass 12.

43. Claim 61 is drawn to an isolated polypeptide (SEQ ID NO:12), classified in class 530, subclass 350.

44. Claims 62-63 are drawn to an isolated polynucleotide (SEQ ID NO:11), classified in class 536, subclass 23.1.

45. Claims 64-65 are drawn to a method of screening a compound for effectiveness as an antagonist, pertaining to SEQ ID NO:12, classified in class 435, subclass 7.1.

46. Claims 66-67 are drawn to a method for an antagonist compound for effectiveness in altering expression of a target nucleic acid, pertaining to SEQ ID NO:11, classified in class 435, subclass 6.

47. Claim 68 is drawn to a method for treatment of an individual having need to inhibit the polypeptide, pertaining to SEQ ID NO:12, classified in class 514, subclass 2.

48. Claim 69 is drawn to a vaccine, pertaining to SEQ ID NO:12, classified in class 435, subclass 43.

49. Claim 70 is drawn to a method of preventing or treating a microbial infection, pertaining to SEQ ID NO:12, classified in class 514, subclass 12.

50. Claim 71 is drawn to an isolated polypeptide (SEQ ID NO:21), classified in class 530, subclass 350.

51. Claims 72-73 are drawn to an isolated polynucleotide (SEQ ID NO:20), classified in class 536, subclass 23.1.

52. Claims 74-75 are drawn to a method of screening a compound for effectiveness as an antagonist, pertaining to SEQ ID NO:21, classified in class 435, subclass 7.1.

53. Claims 76-77 are drawn to a method for an antagonist compound for effectiveness in altering expression of a target nucleic acid, pertaining to SEQ ID NO:20, classified in class 435, subclass 6.

54. Claim 78 is drawn to a method for treatment of an individual having need to inhibit the polypeptide, pertaining to SEQ ID NO:21, classified in class 514, subclass 2.

55. Claim 79 is drawn to a vaccine, pertaining to SEQ ID NO:20, classified in class 435, subclass 43.

56. Claim 80 is drawn to a method of preventing or treating a microbial infection, pertaining to SEQ ID NO:21, classified in class 514, subclass 12.

57. Claim 81 is drawn to an isolated polypeptide (SEQ ID NO:24), classified in class 530, subclass 350.

58. Claims 82-83 are drawn to an isolated polynucleotide (SEQ ID NO:23), classified in class 536, subclass 23.1.

59. Claims 84-85 are drawn to a method of screening a compound for effectiveness as an antagonist, pertaining to SEQ ID NO:24, classified in class 435, subclass 7.1.

60. Claims 86-87 are drawn to a method for an antagonist compound for effectiveness in altering expression of a target nucleic acid, pertaining to SEQ ID NO:23, classified in class 435, subclass 6.

61. Claim 88 is drawn to a method for treatment of an individual having need to inhibit the polypeptide, pertaining to SEQ ID NO:24, classified in class 514, subclass 2.

62. Claim 89 is drawn to a vaccine, pertaining to SEQ ID NO:24, classified in class 435, subclass 43.

63. Claim 90 is drawn to a method of preventing or treating a microbial infection, pertaining to SEQ ID NO:24, classified in class 514, subclass 12.

64. Claim 91 is drawn to an isolated polypeptide (SEQ ID NO:27), classified in class 530, subclass 350.

65. Claims 92-93 are drawn to an isolated polynucleotide (SEQ ID NO:2), classified in class 536, subclass 23.1.

66. Claims 94-95 are drawn to a method of screening a compound for effectiveness as an antagonist, pertaining to SEQ ID NO:27, classified in class 435, subclass 7.1.

67. Claims 96-97 are drawn to a method for an antagonist compound for effectiveness in altering expression of a target nucleic acid, pertaining to SEQ ID NO:2, classified in class 435, subclass 6.

68. Claim 98 is drawn to a method for treatment of an individual having need to inhibit the polypeptide, pertaining to SEQ ID NO:27, classified in class 514, subclass 2.

69. Claim 99 is drawn to a vaccine, pertaining to SEQ ID NO:27, classified in class 435, subclass 43.

70. Claim 100 is drawn to a method of preventing or treating a microbial infection, pertaining to SEQ ID NO:27, classified in class 514, subclass 12.

2. The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention 2, 9, 16, 23, 30, 37, 44, 51, 58 and 65 are related to the proteins of Invention 1, 8, 15, 22, 29, 36, 43, 50, 57 and 64 by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the

natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Inventions 2, 9, 16, 23, 30, 37, 44, 51, 58, 65 and Inventions 3, 5-7, 10, 12-14, 17, 20-22, 24, 26-28, 31, 33-35, 38, 40-42, 45, 47-49, 52, 54-56, 59, 61-63, 66 and 68-100 are unrelated. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA can be used in a different process for example, in a hybridization assay.

Inventions 1, 8, 15, 22, 29, 36, 43, 50, 57 and Inventions 4, 11, 18, 25, 32, 39, 46, 53, 60 and 67 are unrelated. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein product can be used in a different process for example, to make antibodies.

The methods of inventions 4, 11, 18, 25, 32, 39, 46, 53, 60, 67, 3, 5-7, 10, 12-14, 17, 20-22, 24, 26-28, 31, 33-35, 38, 40-42, 45, 47-49, 52, 54-56, 59, 61-63, 66 and 68-100 are patentably distinct, having different products, different endpoints and different method steps.

Inventions 1, 8, 15, 22, 29, 36, 43, 50, 57 and Inventions 3, 5-7, 10, 12-14, 17, 20-22, 24, 26-28, 31, 33-35, 38, 40-42, 45, 47-49, 52, 54-56, 59, 61-63, 66 and 68-100 are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein product can be used in a different process for example, a bioassay.

Inventions 2, 9, 16, 23, 30, 37, 44, 51, 58, 65 and 4, 11, 18, 25, 32, 39, 46, 53, 60 and 67 are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA product can be used in a different process for example, to produce probes.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Furthermore, the inventions have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference, which would anticipate the invention of one group, would not necessarily anticipate or make obvious the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized

divergent subject matter, election of a single group for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the

prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:30 p.m.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner 7/18/05

HOPE ROBINSON
PATENT EXAMINER